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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference 29-53886

April 2, 1998

Jose Pereira
Pereira Dairy
3470 Oakdale Road
Winton, California 95388

WARNING LETTER

Dear Mr. Pereira:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on March 23, 1998, by Food and Drug Administration (FDA) Investigators Karen L. Robles and LaVerne Puckett have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On February 22, 1998, you sold a cow (identified by USDA laboratory report number 260593) for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed penicillin in the kidney at 0.27 parts per million (ppm), and in the liver at 0.11 ppm. The tolerance level for penicillin in the uncooked edible tissues of cattle is 0.05 ppm. The analysis also revealed sulfadimethoxine in the liver at 0.93 ppm, and in the muscle at 0.30 ppm. The tolerance level for sulfadimethoxine in the uncooked edible tissues of cattle is 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Within fifteen (15) days of the receipt of this letter, notify our Sacramento resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, California 95814.

Sincerely yours,

Robert B. Johnson for

Patricia Ziobro
District Director
San Francisco District

cc: [redacted]